



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

December 21, 1999

WARNING LETTER NYK 2000-21

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas J. Gray, Jr., President
Mountain Products, Inc.
47 Burdick Road
LaGrangeville, New York 12540

Dear Mr. Gray:

U.S. Food and Drug Administration (FDA) Investigator Denise Terzian performed an inspection at your fish processing facility on November 3, 1999. The inspection covered cold smoked, vacuum-packed salmon. Our findings revealed this product is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. It was produced and held under conditions contrary to 21 CFR 123 which constitute conditions whereby it may have been rendered injurious to health.

As explained in our previous Untitled Letter dated April 29, 1999, the seafood regulations, effective December 18, 1997, require your implementation of a preventative system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate and minimize the likelihood that the identified hazards will occur.

During the inspection, the investigator observed deviations from the principles of HACCP and significant requirements of the program. The investigator also provided you with a copy of the Domestic Seafood HACCP Report (for FDA 3501) which represents her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of most concern to us are as follows:

- (1) Failure to establish a HACCP plan for receiving, processing, and storage of cold, smoked, vacuum packed, salmon, 21 CFR 123.6(b).

Mountain Products, Inc.

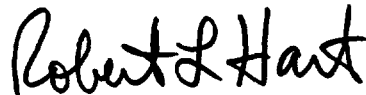
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- (2) Sanitation monitoring records are incomplete. They do not include protection of food, food packaging material, and food contact surfaces from adulterants; proper labeling, storage, and use of toxic compounds; control of employee health conditions; and pest control; 21 CFR 123.11.

You should take prompt action to correct these and all violations at your firm. Failure to achieve correction may result in further regulatory action, without further notice. These actions include seizure and/or injunction.

Please notify this office in writing, within 15 days of the specific steps you have taken to correct the noted violations and prevent reoccurrence of similar violations. Your response should be directed to William J. Thompson, Compliance Officer, at the above address.

Sincerely,



Brenda J. Holman
District Director

